

**Notice of Allowability**

Application No.

09/297,668

Applicant(s)

GERSHONI ET AL.

Examiner

Jeffrey Fredman

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1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to February 10, 2005.
2. ☒ The allowed claim(s) is/are 144,145,149,159,160,163,176,179,191 and 192.
3. ☐ The drawings filed on \_\_\_\_\_ are accepted by the Examiner.
4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☒ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☒ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  6. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |  |   |
|--|---|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892)   | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)           |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 6. <input type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date _____ |
| 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),<br>Paper No./Mail Date <u>3/1/05, 12/27/04</u> | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment                   |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material                                       | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance  |
|  | 9. <input type="checkbox"/> Other _____   |

JEFFREY FREDMAN  
PRIMARY EXAMINER

4/14/05

### **EXAMINER'S AMENDMENT**

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Roger Browdy on April 14, 2005.

The application has been amended as follows:

Claims 184, 185 and 196-221 were cancelled without prejudice towards further prosecution.

2. The following is an examiner's statement of reasons for allowance: The allowed claims are drawn to a recombination method to produce a peptide that interacts with a discontinuous epitope of a single protein or of a pair of proteins in which the library is created in such a way as to permit any oligonucleotide in the library to ligate with any other oligonucleotide in the library. The previous action indicated that this ligation step was new matter, but in the current amendment, Applicant convincingly pointed to support in the specification that directly and inherently teaches this element.

Consequently, the new matter issue is withdrawn. Therefore, the Miyota WO is not prior art to the current case and the prior art rejections will fall without the teachings of Miyota. Further, the limitation regarding ligation differentiates the invention from Huse, who teaches the formation of a similar library, but who expressly requires a particular

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order of ligation in order to function (though within this prescribed limit the ligation is random).

The newly cited Graf reference does teach the randomly permuted library that is missing from Huse and Stemmer, but Graf contains no suggestion or motivation to screen peptides which result from the library for discontinuous epitopes. The newly cited Nagesha reference is quite close to the invention, but differs in one significant way which renders the current claims nonobvious. Nagesha forms discontinuous epitopes from single proteins, but the fragments of Nagesha do not ligate to form "contiguous" fragments as required by the claim in the most recent amendment. The fragments of Nagesha incorporate a BamHI linker, which is then digested, but some of which will remain and render the fragments not directly contiguous. There is no teaching or suggestion in Nagesha to perform the method without the use of the linkers and PCR and in fact, some teaching away from such an alteration.

Therefore, the prior art does not teach or suggest the claimed invention and the claims are novel and unobvious.


Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Fredman whose telephone number is (571)272-0742. The examiner can normally be reached on 6:30-3:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571)272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Jeffrey Fredman  
Primary Examiner  
Art Unit 1637

4/19/05